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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,058	04/30/2001	Jay K.. Bass	10004190-1	4485

7590 12/29/2005

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EXAMINER	
EPPERSON, JON D	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/846,058	BASS ET AL.	
	Examiner	Art Unit	
	Jon D. Epperson	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28,29,31,35 and 37-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *29,31,35 and 37-44* is/are allowed.

6)☒ Claim(s) *28 and 45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 August 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

1. The Response filed November 7, 2005 is acknowledged.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

3. The new rejection below was not necessitated by Applicants' amendments and, as a result, this action is non-final.

Status of the Claims

4. Claims 1-9 and 28-46 were pending. Applicants amended claims 37, 38 and canceled claims 1-9, 30, 32-34, 36 and 46. Therefore, claims 28, 29, 31, 35 and 37-45 are currently pending and examined on the merits.

Withdrawn Objections/Rejections

5. All previous rejections and/or objections are withdrawn in view of Applicants' arguments and/or amendments. The indication of allowability with respect to claims 28 and 45 is hereby withdrawn in view of the new rejection below.

New Rejections

Claims Rejections - 35 U.S.C. 102

6. Claims 28 and 45 is rejected under 35 U.S.C. 102(e) as being anticipated by Indermuhle et al. (US Patent Application Publication 2001/0036674 A1, now patent US 6,720,157 B2) (Filed on **February 23, 2001**) (of record).

For ***claim 28***, Indermuhle et al. (see entire document) disclose methods for making and using "pillar" biochips (e.g., see Indermuhle et al., abstract; see also figures), which anticipates the claimed invention. Indermuhle et al. disclose **(a)** comparing the height uniformity of a first direction and a second direction across a substrate to identify a first direction having higher height uniformity than a second direction, wherein said first and second directions are planar to said substrate (e.g., see figure 2 where the height of the top of the pillars, element 24(a), is compared to the bottom of the pillars as represented by the "H" on the right hand side of the figure; see also figure 17(d) showing visual comparison of samples 325 and 326 at different heights; see also figure 5 showing visual comparison of pillar heights aligned in columns and/or rows; see also figure 6(i) showing higher height uniformity at the center of the pillars). For example, a column of pillars as shown in figure 5 having the shape as shown in figure 6(i) would have a higher height uniformity, at least with respect to the sample surface, when the samples are deposited on top of the pillars (i.e., aligned with the row) as opposed to some other angle (see picture below).

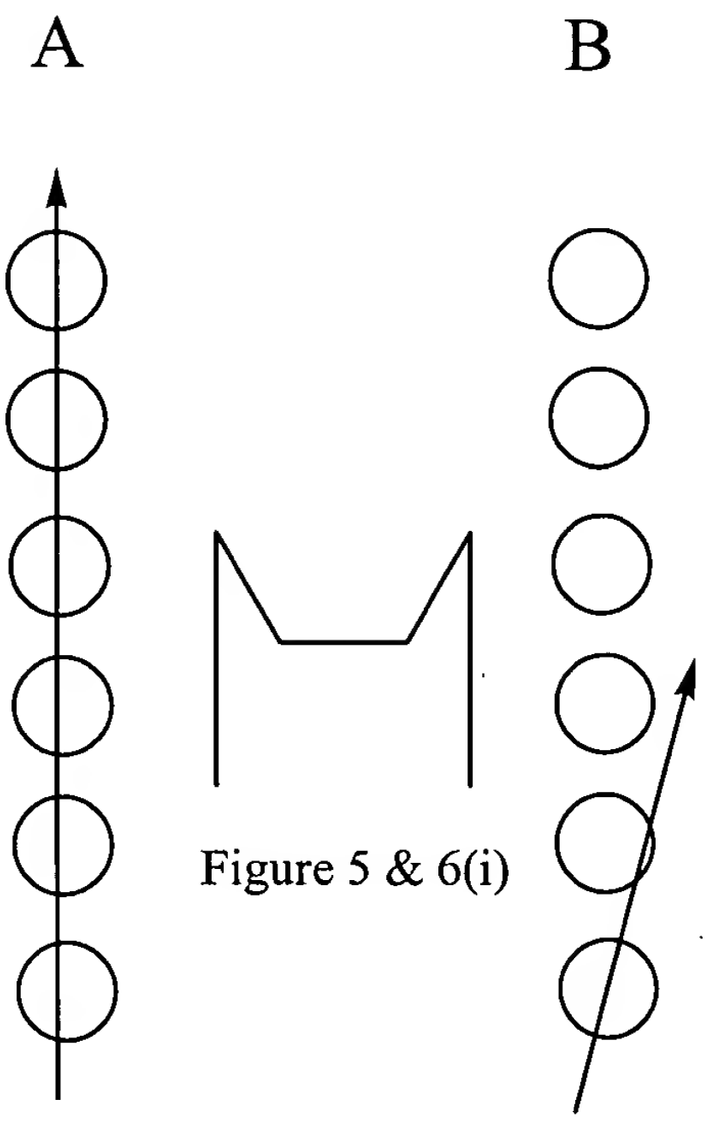
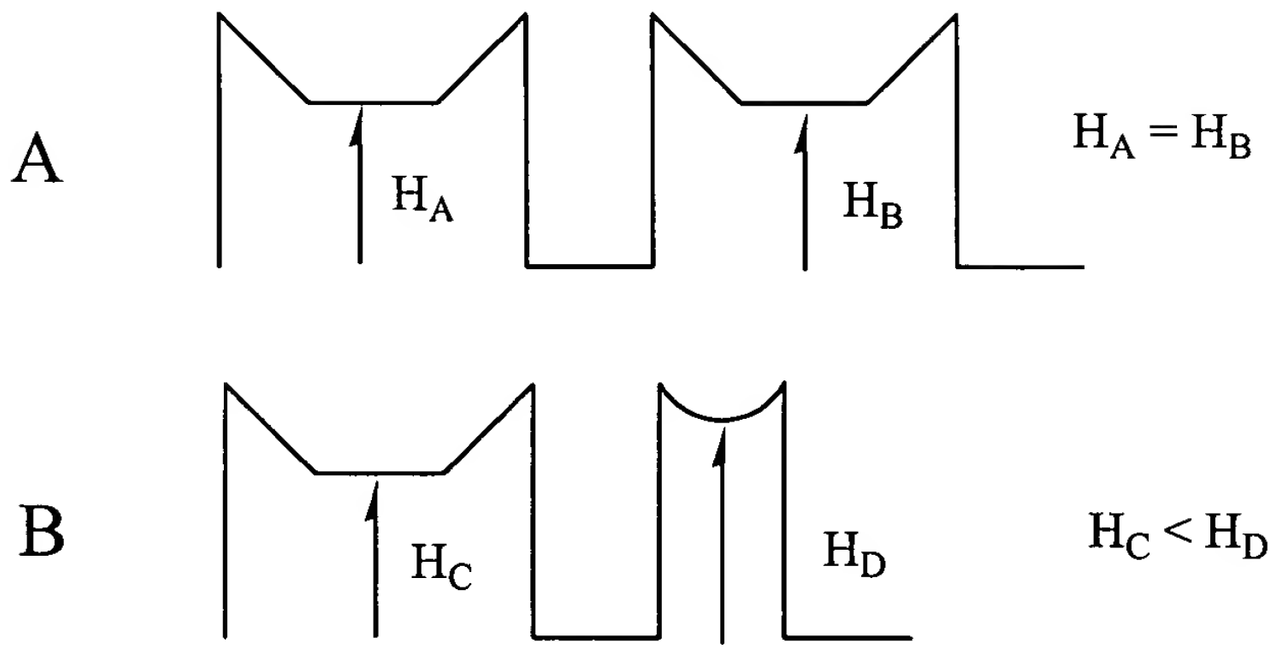


Figure 5 & 6(i)



In this scenario, there is higher height uniformity in the "A" direction than in the "B" direction, at least with respect to the sample surface at the top of the pillar, as shown schematically above. The reference does not explicitly state that the "A" and "B" directions are compared, but the examiner contends that this feature is inherently disclosed by Indermuhle et al. as the height of each pillar in the column is measured (e.g.,

see element "H" to the right of figure 2(a)) and pictures like figure 5 and 6(i) could not be obtained without at least a visual comparison of the heights in all directions. "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The Office does not have the facilities to make such a comparison and the burden is on the applicants to establish the difference. See *In re Best,* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

In addition, Indermuhle et al. disclose the use of a pulse jet printer to deposit different chemical moieties in rows on the substrate, wherein said rows each contain a plurality of different chemical moieties and wherein said rows are more closely aligned with the first direction, direction "A" above, than the second direction, direction "B" above (e.g., see figure 18 showing use of pulse jet printer; see also column 4, Detailed Description of Invention, "Each structure includes a sample surface that is elevated with respect to the non-sample surface of the chip. The sample surface of a structure may correspond to the top surface of the pillar … The samples can be in the form of liquids when they contact the sample surfaces [i.e., the samples are aligned with the top of the pillars]"; see also figure 17(d); see also column 22, paragraphs 3 and 4; see also figure 3 where the "plurality of different chemical moieties" are represented by elements 65, 66 and 67; see also figure 4 showing elements 75 and 75; see also page 2, column 2, paragraph 44, "More specifically, interactions between the following components may be analyzed using embodiments of the invention: antibody/antigen [i.e., the antibody +

antigen represents a "plurality" of different chemical moieties], antibody/hapten [i.e., the antibody + hapten represents a "plurality" of different chemical moieties] … repressor/inducer [i.e., the repressor + induce represent a plurality of different chemical moieties] … and the like"). The layers of silicon oxide (i.e., element 61), titanium oxide (i.e., element 62), polylysine or polyethylene glycol (i.e., element 64) in addition to the biotin (i.e., element 65), streptavidin (i.e., element 66), second adaptor biotin (i.e., element 67) and antibody (i.e., element 68) also fall within the scope of a plurality of different chemical moieties (e.g., see page 6, paragraph 77, "An interlayer 61 [referring to figure 3] including an oxide such as silicon oxide is at the top surface of the pillar 60. The interlayer 61 may be used to bind the coating layer 62 to the pillar 60. The coating layer 62 may include another oxide such as titanium oxide. An affinity structure 69 is on the coating layer 62. The affinity structure 69 may include a monolayer 64 with organic molecules such as polylysine or polyethylene glycol … A set of molecules including a first adaptor molecule 65 such as biotin, an affinity tag 66 such as avidin or streptavidan, a second adaptor molecule 67 such as biotin, and a capture agent 68 such as an antibody are linked together … it is understood that in embodiments of the invention, many such sets of molecules may be present on the monolayer 64.").

Finally, Indermuhle et al. disclose the fabrication of an array of multiple features of different chemical moieties on the substrate surface (e.g., see Indermuhle et al., figure 24 disclosing the array of pillars on the surface wherein various chemicals are spotted on said surface; see also page 2, column 2, paragraph 44; see also figures 2-4; see also page

3, column 2, paragraph 55). Also note that the "first" and "second" directions are perpendicular to the edges of the substrate (i.e., they are perpendicular to each other).

For ***claim 45***, Indermuhle et al. (see entire document) disclose methods for making and using "pillar" biochips including the use of "elongated" pillars (see Indermuhle et al., abstract; see also figures 24-25), which anticipates the claimed invention. For example, Indermuhle et al. disclose **(a)** comparing the height uniformity of a first direction and a second direction across a substrate to identify a first direction having higher height uniformity than a second direction, wherein said first and second directions are planar to said substrate (e.g., see Indermuhle et al., figure 24). For example, the top of element 132 in figure 24 displays a rectangle wherein a direction that is parallel to the longer edge of the rectangle (i.e., the direction labeled "Y" in figure "B" on page 4 of the 2/8/05 rejection) has a higher height uniformity than a direction that is parallel to the shorter edge of the rectangle (i.e., the direction labeled "X" in figure "A" on page 3 of the 2/8/05 rejection).

Here, both directions (i.e., X and Y) are in the plane of the substrate, but the "Y" direction (see figure B on page 4 of the 2/8/05 rejection) has higher height uniformity because the top of the rectangular pillar extends almost continuously across the entire length of the substrate without any variation in the height. In contrast, the "X" direction (see figure A on page 3 of the 2/8/05 rejection) extends across many pillars (e.g., elements 132 and 135; see also figure 24 wherein "9" 132 pillars are shown), spaces that separate the pillars (e.g., element 134 in figure 24), and many channel defining walls (e.g., "2" 135 pillars are shown in figure 24). Thus, the "height" is less uniform

proceeding along the "X" direction than the "Y" direction (compare figures A and B on page 3 and 4 of the 2/8/05 rejection) because the height changes from pillar (i.e., element 132) to space between the pillars (i.e., element 134 in figure 24) to channel defining wall elements (i.e., element 135) (see also figure A above wherein vertical "arrows" depict all the changes in height as one proceeds along the "X" direction). In addition, the X and Y directions have been "visually compared" because figure 24 shows the "alignment" of the top piece (e.g., elements 130 and 133) parallel to the elongated axis of the pillars (e.g., elements 132 and 135). That is the top piece only "fits" in "one direction" and thus the heights must be "visually compared" in order to make this fit and/or alignment as explicitly shown in figure 24 or, in the alternative, the "comparison" was inherently made at the "fitting" and/or "design" stages (i.e., when the plates were put together OR when the bottom plate was individually fabricated). That is, the plates were designed to "fit together", which takes into account a comparison of the heights along the "X" and "Y" directions to insure that the top plate fits into the bottom plate both when the plates were made and when the plates are actually fitted together. If this were not the case, then the plates wouldn't fit together and sample would be placed in the "wells" between the pillars as a result of misalignment. "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The Office does not have the facilities to make such a comparison and the burden is on the applicants to establish the difference. See *In re Best,* 562 F.2d 1252, 195

USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

In addition, Indermuhle et al. disclose **(b)** placing different chemical moieties in row on the substrate so as to provide a row of different chemical moieties that is more closely aligned with the first direction than the second direction, in order to fabricate an array fo multiple feaures of different chemical moieties on a substrate surface (e.g., see Indermuhle et al., figure 24, wherein element 133 is used to "dispense" chemical on the top of the elongated pillars "rows" (i.e., element 132) that are parallel (i.e., closely aligned to the first direction); see also page 2, column 2, paragraph 44 which discloses numerous chemical moieties that can be deposited on the pillar e.g., antibody/antigen, enzyme/substrate, etc.). In addition, Indermuhle et al. placing the different chemical moieties in rows on the substrate wherein said rows each contain a plurality of different chemical moieties (e.g., see figure 3 where the "plurality of different chemical moieties" are represented by elements 65, 66 and 67; see also figure 4 showing elements 75 and 75; see also page 2, column 2, paragraph 44, "More specifically, interactions between the following components may be analyzed using embodiments of the invention: antibody/antigen [i.e., the antibody + antigen represents a "plurality" of different chemical moieties], antibody/hapten [i.e., the antibody + hapten represents a "plurality" of different chemical moieties] … repressor/inducer [i.e., the repressor + induce represent a plurality of different chemical moieties] … and the like"). The layers of silicon oxide (i.e., element 61), titanium oxide (i.e., element 62), polylysine or polyethylene glycol (i.e., element 64) in addition to the biotin (i.e., element 65), streptavidin (i.e., element

66), second adaptor biotin (i.e., element 67) and antibody (i.e., element 68) also fall within the scope of a plurality of different chemical moieties (e.g., see page 6, paragraph 77, "An interlayer 61 [referring to figure 3] including an oxide such as silicon oxide is at the top surface of the pillar 60. The interlayer 61 may be used to bind the coating layer 62 to the pillar 60. The coating layer 62 may include another oxide such as titanium oxide. An affinity structure 69 is on the coating layer 62. The affinity structure 69 may include a monolayer 64 with organic molecules such as polylysine or polyethylene glycol … A set of molecules including a first adaptor molecule 65 such as biotin, an affinity tag 66 such as avidin or streptavidan, a second adaptor molecule 67 such as biotin, and a capture agent 68 such as an antibody are linked together … it is understood that in embodiments of the invention, many such sets of molecules may be present on the monolayer 64.").

Finally, Indermuhle et al. disclose the fabrication of an array of multiple features of different chemical moieties on the substrate surface (e.g., see Indermuhle et al., figure 24 disclosing the array of pillars on the surface wherein various chemicals are spotted on said surface; see also page 2, column 2, paragraph 44; see also figures 2-4; see also page 3, column 2, paragraph 55). Also note that the "first" and "second" directions are perpendicular to the edges of the substrate (i.e., they are perpendicular to each other).

Allowable Subject Matter

7. Claims 29, 31, 35 and 37-44 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D.
December 21, 2005

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